

Advanced Sterilization Products (ASP) Sterrad Cyclesure 24 Biological Indicator: Safety Communication – Potential Risk of Infection (7/12)

AUDIENCE: Risk Manager, Surgery, Infectious Disease

ISSUE: An FDA review of ASP data showed that certain lots of the Sterrad Cyclesure 24 Biological Indicators cannot effectively monitor the sterilization process throughout the indicated 15-month shelf life. After reviewing additional ASP data, the FDA believes that the product may be used with a 6-month shelf life. ASP made a change in December 2011 to the materials used to manufacture the product. Product lots manufactured prior to this material change are not subject to the recall.

BACKGROUND: The Sterrad Cyclesure 24 Biological Indicator is a product used periodically to monitor and confirm the microbicidal effectiveness of the sterilization process in Sterrad sterilizers. A biological indicator is used, in conjunction with other methods, to monitor sterilization systems. Sterrad sterilizers are used for devices that must be sterilized at low temperatures, such as multiple single-channel flexible endoscopes, cameras, some rigid scopes, light cords, batteries, and power drills. ASP's Sterrad Cyclesure 24 Biological Indicator is the only biological indicator that can be used with the Sterrad sterilizer. Biological indicators from other manufacturers are not designed for this use and have not been cleared by the Food and Drug Administration (FDA) for use in Sterrad sterilizers.

RECOMMENDATIONS:

- If your facility has purchased Sterrad Cyclesure 24 Biological Indicators and product remains on hand, a new expiration date can be calculated as follows: [Printed Expiration date (minus) 9 months = new expiration date].
- Refer to the list of affected lots found in ASP's Recall Alert <http://www.aspii.com/us/news/cyclesureletter> to determine if the product in inventory is subject to this recall.
- Manually re-label the non-expired product cases with the newly calculated expiration date.
- Use an alternative low-temperature sterilizer, if available. In order to conserve the amount of non-expired product available in your facility, only use low-temperature sterilization for those items that cannot be sterilized using other methods.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm 1
- [Download](#) form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the preaddressed form, or submit by fax to 1-800-FDA-0178.

Please include the following information in your reports, if available

- Adverse event details (date adverse event occurred, nature of the event)
- Expiration date and/or lot number listed on the Sterrad Cyclesure 24 Biological Indicators